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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

JONNIE HOMYK, et al.,
Plaintiffs,

v.

CHEMOCENTRYX, INC. et al.,

Defendants.

Master File No. 4:21-cv-03343-JST *and related case*, No. 4:21-cv-04357

LEAD PLAINTIFF'S OPPOSITION TO DEFENDANTS' ADMINISTRATIVE MOTION TO FILE UNDER SEAL

Lead Plaintiff Indiana Public Retirement System ("Lead Plaintiff") respectfully submits this opposition to Defendants' Motion to File Under Seal ("Motion" (ECF No. 325)), which seeks to seal portions of their summary judgment reply brief, as well as portions of two exhibits cited therein (the "Documents"). For each of the following reasons, sealing is unwarranted.

First, the Court has already issued two orders rejecting Defendants' identical sealing arguments and denying their identical requests to seal the identical categories of documents at the summary judgment stage. *See* ECF Nos. 304, 305.

Second, Defendants' Motion again skips past the legal standard. At the summary judgment stage, sealing is improper absent "compelling reasons supported by specific factual findings that outweigh the general history of access and the public policies favoring disclosure, such as the public interest in understanding the judicial process." *Kamakana v. City and Cnty. of Honolulu*, 447 F.3d 1172, 1178, 1180 (9th Cir. 2006) ("[D]ispositive motions [treated] differently.").

"Additionally, because of the peculiar posture of class actions whereby some members of the public are also parties to the class action, … the test for overriding the right of access should be applied in this case with particular strictness." *In re Cendant Corp.*, 260 F.3d 183, 194 (3d Cir. 2001); *see also Marsh v. First Bank of Delaware*, 2014 WL 117086, at *1 (N.D. Cal. Jan. 13, 2014) ("In a class action, the public right of access to court documents is especially heightened.").

Third, the Court has already found that evidence of Defendants' data manipulation supports Plaintiff's claims, rejecting Defendants' contentions that such evidence is "irrelevant" and charges "unpled" conduct. As the Court explained in its May 21, 2025 *Daubert* Order ("Order" (ECF No. 275)), "contrary to Defendants' characterization of this opinion as supporting an 'unpled theory,' the Court finds that testimony on the unblinded review does not assert a separate theory of liability but rather supports the scienter element of Plaintiff's claims." Order at 10. The Court further held that evidence on the subject "is generally relevant to Defendants' knowledge that their alleged misrepresentations were false in this case — i.e., that avacopan in fact failed to achieve statistically significant superiority." *Id.*

There is nothing "untrue" or "potentially libelous" about the facts. The record makes plain that, among other things: (i) on November 5, 2019, following the completion of quality control

measures, the ADVOCATE database was locked (i.e., no changes could be made) (ECF No. 229.15 ¶¶105, 115); (ii) on November 8, 2019, ChemoCentryx's top medical officer, Dr. Pirow Bekker learned that the ADVOCATE study failed to meet its week 52 superiority endpoint (*id.* at ¶105); (iii) according to Dr. Schall's private instruction to Dr. Bekker sent via text message, Dr. Bekker was to immediately call Dr. Schall if his review of the unblinded data showed a failure to meet the week-52 "superiority" endpoint; (iv) on November 9, 2019, Dr. Bekker instructed his colleague to review the data and the results, stating "we cannot afford to miss a superiority outcome here" (Ex. 108 at 878), but no inconsistences were found (ECF No. 229.15 ¶106);[1] (v) Dr. Bekker then carried out an unblinded review of the data and identified five patients in the avacopan arm of ADVOCATE who, if switched from "non-responder" to "responder" would allow ChemoCentryx to claim it met its week-52 superiority endpoint (Ex. 111; ECF No. 316.11); (vi) the likelihood of Dr. Bekker identifying by chance only patients in the avacopan arm and only switches from "non-responder" to "responder" is less than 3% (ECF No. 201.11 ¶68, n. 85); (vii) Dr. Bekker's unblinded review contravened both the ADVOCATE protocol, which stated that the data must be "adjudicated, according to an adjudication charter, before data finalization and unblinding" (Ex. 112 at 492), and the Adjudication Committee Charter, which stated "[a]t the time of database lock, all the 52-week BVAS data entered by the sites will be 100% source verified and cleaned ... and no changes may be [made] after data base lock" (ECF No. 282.24 at 198); (viii) Dr. Bekker successfully compelled Dr. Jayne to switch the five avacopan patients from "non-responders" to "responders," even though these patients were deemed "non-responders" based on the rules he developed in consultation with ChemoCentryx's prior CMO to "address the subjectivity" and "impose a strict control" on the primary endpoint determination (Ex. 114 at 973); (ix) on November 25, 2019, ChemoCentryx issued a press release drafted by Dr. Schall and Dr. Bekker, which claimed that ADVOCATE met its week 52 superiority endpoint (Ex. 7); and (x) the next day, Dr. Schall and Dr. Bekker unloaded a half million of their personal shares,

[1] "Ex." refers to the exhibits attached to the May 8, 2025 Declaration in Support of Lead Plaintiff's Motion for Partial Summary Judgment (ECF No. 268) and the June 19, 2025 Declaration in Support of Lead Plaintiff's Opposition to Defendants' Cross-Motion for Summary Judgment and Lead Plaintiff's Reply In Support of Motion for Partial Summary Judgment (ECF No. 301).

collecting proceeds of $15 million.

Far from "untrue" or "potentially libelous," the evidentiary record is also supported by sworn testimony of witnesses and experts in the field. *See, e.g.*, Ex. 151 ¶3 (testimony of Dr. Walton that Defendants' data manipulation violated the ADVOCATE protocol,"rais[ing] concerns about the integrity of the study as whole"); ECF No. 102.14 at 318:13-319:5 (testimony of Dr. Glassock that "it would be scientifically improper for a sponsor to learn the unblinded results of a trial and then start changing patient scores," and it would "[v]ery substantially … undermine the medical community's confidence in the integrity of the results"); ECF No. 229.34 at 261:2-10 (testimony of Dr. Chalasani that "after unblinding, if a patient moved [from] nonresponder to responder, that seems problematic to me"); *see also* Order at 9; ECF No. 201.11 ¶71 (approving Dr. Madigan to testify how "selection of patients for post-database lock readjudication based on an unblinded review introduced bias into the study, violated the ADVOCATE Protocols blinding provisions, and invalidates the study's results"); Order at 16; ECF No. 229.15 ¶111 (approving Dr. Helfgott to testify "why he disagrees with the rationales offered by ChemoCentryx doctors for changing th[e] results … for the five avacopan patients").

Evidence of data manipulation is powerful proof of scienter, as courts have repeatedly found. If Defendants had not manipulated the ADVOCATE trial results, they would have, among other things, been forced to admit to investors that the FDA specifically rejected "non-inferiority" at week-52 as a primary endpoint and, as a result, the study failed. *See, e.g.*, Ex. 66 at 646 ("a demonstration of non-inferiority would not be sufficient"); Ex. 67 at 029 ("[W]e do not agree with your statements … which indicate that you will conclude to have a successful study" based on non-inferiority); *see also In re Entropin, Inc. Sec. Litig.*, 487 F. Supp. 2d 1141, 1148-52 & n.10 (C.D. Cal. 2007) ("unblinding" and "manipulation" of clinical data created a "material issue of fact" on scienter); *Nathanson v. Polycom, Inc.*, 87 F. Supp. 3d 966, 979-80 (N.D. Cal. 2015) (circumstantial scienter evidence includes cover-up evidence).

Plus, ChemoCentryx's data manipulation takes on heightened import in this case, if Defendants are permitted to introduce evidence to the jury of the FDA's "approval" of TAVNEOS after the Class Period. Indeed, TAVNEOS would never have been approved by the FDA if

ChemoCentryx had not manipulated the ADVOCATE study results after it was unblinded, as the study would have failed to meet its week-52 superiority endpoint. And as Defendants' motion for summary judgment now makes plain, Defendants' primary (and misguided) defense in this case—if permitted—would be that the FDA's "approval" after the Class Period provided them license to mislead investors during the Class Period.

Fourth, Defendants have not met their burden on this Motion. "The compelling reasons standard is demanding and potential harm to business or litigation strategies is not enough." *Scholz-Gross v. Starbucks Corp.*, 2019 WL 13201909, at *2 (N.D. Cal. Feb. 8, 2019). As this Court has stressed, "'broad allegations of harm, unsubstantiated by specific examples or articulated reasoning,' do not even satisfy the lower 'good cause' standard." *In re Twitter Inc. Sec. Litig.*, 2020 WL 2519888, at *2 (N.D. Cal. May 18, 2020). Moreover, "[t]he mere fact that the production of records may lead to a litigant's embarrassment, incrimination, or exposure to further litigation will not, without more, compel the court to seal its records." *Kamakana*, 447 F.3d at 1179. And "conclusory offerings [in support of sealing] do not rise to the level of 'compelling reasons' sufficiently specific to bar the public access." *Id.* at 1182, 1184 (requiring a specific compelling reason for each redaction rather than "a general category of privilege").

Once again, Defendants' lone support for their sealing motion is a declaration by trial counsel (not any Amgen employee[2]) that states in conclusory fashion that the lumped-together "Confidential Materials" "contain proprietary and commercially sensitive information about the ADVOCATE clinical trial" and would cause (unspecified) "substantial harm." ECF No. 325-1 ¶¶6-7. This is not nearly enough. *See, e.g.*, *Twitter*, 2020 WL 2519888, at *2 ("Defendants motion and accompanying declaration consist merely of generic assertions that the [sealed document] contains 'highly sensitive, confidential, and proprietary information, including non-public information about Twitter's operating metrics.'"); *FibroGen, Inc. v. Hangzhou Andao Pharm. Ltd.*, 2023 WL 6237986, at *3 (N.D. Cal. Sept. 22, 2023) ("FibroGen 'may not rely on vague boilerplate

[2] A declaration by trial counsel "that disclosure of the materials would injure [defendants]'s business … is entitled to no weight" where, as here, the trial counsel does not "explain how he has personal knowledge of [defendant]'s business operations." *Signal Hill Serv., Inc. v. Macquarie Bank Ltd.*, 2013 WL 12244287, at *3 (C.D. Cal. May 14, 2013) (citing cases).

language or nebulous assertions of potential harm but must explain with particularity why any document or portion thereof remains sealable under the applicable legal standard."'); *Tevra Brands LLC v. Bayer HealthCare LLC*, 2020 WL 1245352, at *3 (N.D. Cal. Mar. 16, 2020) ("[Bayer's] blanket claims that their 'competitive standing[s] could be significantly harmed' by disclosure are not only conclusory and vague, they also generalize across all the information sought to be sealed."); *U.S. Ethernet Innovations, LLC v. Acer, Inc.*, 2013 WL 4426507, at *2 (N.D. Cal. Aug. 14, 2013) ("Intel provides no specific facts or explanation of … how it would be hurt competitively and why it expects that this would result from public disclosure of this material.").

Finally, contrary to the declaration of Defendants' counsel (ECF No. 325 ¶5), Defendants do not seek to redact any "patient information, raw trial data, [or] clinical trial strategy." Indeed, none of the redactions remotely references "any patient information, raw trial data, [or] clinical trial strategy." And even if they did, that would not justify their sealing at the summary judgment stage. *See Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1137 (9th Cir. 2003) ("We do not see how the presence of a small number of third-party medical and personnel records that can be redacted with minimal effort constitutes 'good cause,' let alone a compelling reason … to overcome the strong presumption in favor of public access."); *see also Contratto v. Ethicon, Inc.*, 227 F.R.D. 304, 310 (N.D. Cal. 2005) (denying motion to seal "record of an adverse event experienced by a patient who used" study drug, with appropriate redactions to the "name of the patient").

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